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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,998

08/18/2003

John D. Hatlestad

GUID.058PA

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51294

7590

02/08/2006

HOLLINGSWORTH & FUNK, LLC

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EXAMINER

STALLARD, JOSEPH A

ART UNIT

PAPER NUMBER

3715

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/642,998	Applicant(s) HATLESTAD ET AL.	
	Examiner J. Andrew Stallard	Art Unit 3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/20/2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 and 57-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 35-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/05; 6/04; 1/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-14 and 35-56 in the reply filed on 12/20/2005 is acknowledged.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 and 35-56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

For a claimed invention to be statutory, the claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." See MPEP 2106.II.A.

In the present case, the claims are drawn to a method of collecting and evaluating data, but neither the collected data nor the evaluations produce a useful, concrete and tangible result. Furthermore, there is no practical application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-14 and 35-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Cho et al. (US 6,641,542).

Claim 1: Cho discloses a method for collecting sleep quality data, comprising: detecting physiological and non-physiological conditions associated with sleep quality of a patient (*col. 4, 40-42; The invention can be used to detect conditions related to sleep apnea, which effects the sleep quality of a patient. Body movement, which is a non-physiological condition, is detected with the body movement sensor (520; col. 6, 54).;* and collecting sleep quality data based on the detected conditions, wherein collecting the sleep quality data is performed at least in part implantably (*col. 3, 14-16; An implantable sensor is used in the collecting of data related to sleep apnea.*).

Claim 2: Cho discloses that detecting the conditions comprises detecting a cardiovascular system condition (*col. 8, 28-32; Hypertension is detected, which is a cardiovascular system condition.*).

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Claim 3: Cho discloses that detecting the conditions comprises detecting a respiratory system condition (*col. 3, 14-23; Respiratory system conditions such as Cheyne-Stokes respiration are detected.*).

Claim 4: Cho discloses that detecting the conditions comprises detecting a muscle system condition (*col. 7, 19-21*).

Claim 5: Cho discloses that detecting the conditions comprises detecting a blood chemistry condition (*col. 8, 3-7*).

Claim 6: Cho discloses that detecting the conditions comprises detecting a nervous system condition (*col. 8, 61-64; Cheyne-Stokes respiration is detected. Central sleep apnea (CSA) is a neurological condition, or in other words, nervous system condition (col. 1, 32-36). Cheyne-Stokes respiration is a form of central sleep apnea (col. 1, 44-45).*).

Claim 8: Cho discloses that detecting the conditions comprises detecting a contextual condition (*col. 6, 57-65; Limb movements are a non-physiological condition. According to the present application contextual conditions are non-physiological conditions (p. 11, line 29)*).

Claim 9 and 37: Cho discloses that collecting the sleep quality data comprises collecting data associated with sleep stages (*col. 3, 14-17; sleep cycle length*).

Claim 10 and 38: Cho discloses that collecting the sleep quality data comprises collecting data associated with sleep disruption (*col. 6, 57-65; abnormal arousals*).

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Claim 11 and 39: Cho discloses that collecting the sleep quality data comprises collecting data associated with disordered breathing (*col. 3, 14-23; periodic breathing, Cheyne-Stokes respiration*).

Claim 12 and 40: Cho discloses that collecting the sleep quality data comprises collecting data associated with a movement disorder (*col. 6, 57-65; limb movements*).

Claim 13: Cho discloses storing the collected sleep quality data (*col. 5, 35-38; The data is stored in the device 220*).

Claim 14: Cho discloses transmitting the collected sleep quality data (*col. 8, 39-45; Results may be transmitted*).

Claim 35: Cho discloses a method for assessing sleep quality of a patient, comprising: detecting physiological and non-physiological conditions associated with the sleep quality of the patient (*col. 4, 40-42*); collecting sleep quality data based on the detected conditions (*col. 3, 14-16*); and evaluating the sleep quality of the patient using the collected data (*col. 9, 54-56; Sleep quality is evaluated as to whether therapy needs to be administered*), wherein at least one of collecting the sleep quality data and evaluating the sleep quality is performed at least in part implantably (*col. 3, 14-16*).

Claim 36: Cho discloses that both collecting the sleep quality data and evaluating the sleep quality are performed at least in part implantably (*col. 9, 56-59; Evaluation can be performed in the processor (310), which is part of the implantable device (220)*).

Claim 41: Cho discloses that evaluating the sleep quality comprises determining one or more metrics associated with sleep quality (*col. 3, 24-38; Metrics associated with sleep apnea are gathered and diagnosed*).

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Claim 42: Cho discloses that evaluating the sleep quality comprises trending one or more metrics associated with sleep quality over time (*col. 8, 52-60; Number of apneas over time is measured.*).

Claim 43: Cho discloses that evaluating the sleep quality comprises determining one or more metrics associated with disordered breathing (*col. 3, 14-23*).

Claim 44: Cho discloses that evaluating the sleep quality comprises determining one or more metric associated with movement disorders (*col. 6, 57-65*).

Claim 45: Cho discloses that evaluating the sleep quality comprises determining one or more composite metrics based on metrics associated with sleep and metrics associated with events that disrupt sleep (*col. 6, 57-65*).

Claim 46: Cho discloses transmitting at least one of the sleep quality data and the sleep quality evaluation to a separate device (*col. 8, 39-45*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (US 6,641,542) in view of Sullivan et al. (US 5,245,995).

Cho discloses applicant's basic inventive concept of a method for collecting sleep quality data, substantially as claimed, but does not expressly disclose detecting an environmental condition. Sullivan shows this feature to be old in the sleep art. Sullivan discloses that a patient's sleep quality will decrease in an unfamiliar environment (*col.* 3, 34-38). Sullivan teaches that a proper environment is important to obtain the most accurate data (*col.* 3, 34-44). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Sullivan to modify the method of Cho by detecting the environmental conditions as taught by Sullivan to collect the most accurate data.

Claims 47-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (US 6,641,542) in view of Lindenthaler (US 6,361,494).

Claim 47: Cho discloses a method for evaluating sleep quality, comprising: collecting sleep quality data based on the detected one or more conditions (*col.* 3, 14-16); and evaluating the sleep quality of the patient using the collected sleep quality data (*col.* 9, 54-56), wherein at least one of collecting the sleep quality data and evaluating the sleep quality is performed at least in part implantably (*col.* 3, 14-16). Cho does not expressly disclose detecting one or more conditions associated with the sleep quality of a patient during a period of wakefulness. Lindenthaler shows this feature to be old in the sleep art. Lindenthaler discloses measuring muscle activity in the pharyngeal airways and

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sleep apnea while the subject is awake (*col. 1, 61-63*). Lindenthaler teaches this is convenient and increases availability of testing to patients (*col. 1, 63-65*). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Lindenthaler to modify the method of Cho by using the measuring of sleep conditions during a period of wakefulness of Lindenthaler to make the invention more convenient and increase availability of testing to patients.

Claim 48: Cho discloses that detecting the one or more conditions comprises detecting a physiological condition (*col. 8, 28-32*).

Claim 49: Cho discloses that detecting the one or more conditions comprises detecting a non-physiological condition (*col. 6, 54; Body movement, which is a non-physiological condition, is detected with the body movement sensor.*).

Claim 50: Cho discloses that detecting the one or more conditions comprises detecting a nervous system condition (*col. 8, 61-64*).

Claim 51: Cho discloses that detecting the one or more conditions comprises detecting a cardiovascular system condition (*col. 8, 28-32*).

Claim 52: Cho discloses that detecting the one or more conditions comprises detecting patient activity; and collecting the sleep quality data comprises collecting data associated with the patient activity during the period of wakefulness (*col. 11, 10-21; Data about whether a patient is awake or asleep can be detected. Said data can be updated when the patient is aroused from sleep (col. 11, 14-19).*).

Claim 53: Cho discloses storing the collected sleep quality data (*col. 5, 35-38*).

Claim 54: Cho discloses transmitting the collected sleep quality data (*col. 8, 39-45*).

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Claim 55: Cho discloses that evaluating the sleep quality comprises determining one or more sleep quality metrics (*col. 3, 24-38*).

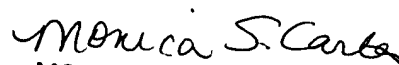
Claim 56: Cho discloses transmitting at least one of the sleep quality data and the sleep quality evaluation to a separate device (*col. 8, 39-45*).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Andrew Stallard whose telephone number is (571) 272-2685. The examiner can normally be reached on 9:15 am to 6:45 pm - Mon - Fri (1st Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Monica S. Carter can be reached on (571) 272-4475. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MONICA CARTER
SUPERVISORY PATENT EXAMINER

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J. Andrew Stallard
Examiner
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